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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,219	07/09/2001	Mark S. Schaberg	54670USA1A.002	6255

7590 09/18/2002

Attention: Robert W. Sprague
Office of Intellectual Property Counsel
3M Innovative Properties Company
P.O. Box 33427
St. Paul, MN 55133-3427

EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	3

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,219	SCHABERG ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed 1/8/2002.

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 1, 4, 5, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,966,902 ('902).

US '902 disclosed a composition comprising a drug in a polymer carrier (abstract). The polymer comprising pyrrolidonoethyl methacrylate polymerized with alkyl acrylate monomer and monomer comprising carboxylic acid (col.2, lines 30-32, 57-58; col.3, lines 1-2, 20-22). The number of carbon atoms are inherent for the monomer.

4. Claims 1 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,123,462 ('462).

US '462 disclosed a polymer comprising alkyl acrylate and pyrrolidonoethyl acrylate (col.2, lines 33-36; col.6, line 36; col.8, lines 44-56).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '902 in view of any of US 6,193,996 ('996) or WO 96/08229 ('229) and may or may not in view of US 2002/0110585 ('585).

The teachings of US '902 is discussed under 102 rejection above. The reference does not teach the macromonomer, the backing for the transdermal delivery, the particular antimicrobial agents, nor the species of the alkyl acrylate.

US '996 teaches a pressure sensitive comprising a copolymer of one or more alkyl acrylates or (meth)acrylates containing 4-12 carbon atoms and one or more hydrophilic monomers. Examples of the alkyl acrylates include butyl, isooctyl, cyclohexyl and 2-ethylhexyl acrylates (abstract; col.2, lines 53-66). Hydrophilic monomers include carboxylic acid containing monomers, vinyl acetate and amino containing monomer (col.3, lines 1-14). The copolymer further comprising macromer, such as polymethylmethacrylate and softener, such as ethylene glycol and propylene glycol (col.3, lines 30-67); col.4, line 61). The above composition is applied into a backing (col.5, lines 21-24).

WO '229 discloses a transdermal drug delivery device comprising a pressure sensitive adhesive comprising copolymer of monomers selected from alkyl acrylate containing 4-12 carbon atoms; monomers comprising functional groups selected from carboxylic acid, sulfonamide, urea, carboxamide, amine, oxy oxo, and cyano;

macromonomer; drug; and softener (page 79, lines 1-25). The copolymer further comprises vinyl acetate or pyrrolidones in an amount of 0-60% (page 80, lines 1-14, 27-30). The alkyl acrylate is selected from isooctyl acrylate, ethylhexyl acrylate, butyl acrylate and cyclohexyl acrylate (page 80, lines 23-25. the macromonomer is present in an amount not more than 15% and is selected from the group containing polymethylmethacrylate (page 81, lines 15-16; page 82, lines 15-18). The softener is present in an amount of 20-60% and selected from fatty acids and fatty alcohols (page 82, lines 20-30).

It is within the skill in the art to select the drug to be delivered transdermally according to particular need. No criticality has been shown in the particular antimicrobial agents of instant claims.

US '585 teaches a transdermal drug delivery device comprising a reservoir comprising copolymer of alkyl methacrylate and monomer having functional group selected from carboxylic acid, sulfonamide, oxy oxo, amine, carbamate, carboxamide, or urea (abstract; page 4, 0039-0041). The drugs to be delivered in this reservoir include iodine compounds and chlorohexidine (page 8, 0101).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to add the additional monomers disclosed by US '996 and WO '229 to the copolymer of US 902 to provide a pressure sensitive adhesive suitable for the transdermal drug delivery, with reasonable expectation of success of the delivered adhesive in transdermal drug delivery. Motivation would arise from the teaching of WO '229 that the copolymer of the invention provide an adhesive that maintains contact with

the skin and can be removed cleanly from the skin (page 3, lines 11-15), or from the teaching of US '996 that the adhesive of the copolymers allow to maintain the device in contact with the skin for a sufficient time (col.2, lines 45-48).

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,732,808 disclosed skin adhesive comprising alkyl acrylate, vinyl acetate, macromer and iodide.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600